Remarks/Arguments

A certified copy of German patent application no. 103 03 229.0 is enclosed herewith to complete applicant's claim for priority under 35 USC 119.

Responsive to the rejection of claims 1-44 under 35 USC 112, first paragraph, independent claim 1 is amended to include via a Markush Group the ACE inhibitors described in the instant application. Reconsideration of the aspect of the § 112 rejection concerning the structural definition of the term "prodrug" in the claims is respectfully requested for the following reasons. Firstly, the term "prodrug" is well understood by those skilled in the art as evidenced by the MSN search printout attached hereto as Exhibit A. Secondly, the description of "prodrugs of ambroxol" at page 11, lines 16-24 of the instant application is believed to be in such full, clear, concise, and exact terms as to enable any person skilled in the art to make and use the same in satisfaction of the requirement of 35 USC 112, first paragraph.

Responsive to the rejection of claims 10-12 under 35 USC 112, first paragraph, these claims have been amended to replace "a prevention and a therapy" with -- treatment --.

Turning now to the Examiner's objections to claims 1-44 set forth on pages 5 and 6 of the Office Action, as described in the instant application the pharmaceutical composition of applicants' invention is the combination of two or more components from a total of three components, those three components being:

1) α-lipoic acid and its salts and isomers;

2) ambroxol and its salts and prodrugs; and

3) inhibitors of the angiotensin-converting enzyme (ACE).

Claim 1 has been amended to substitute -- components -- for "substances" and to set off with semicolons the three components from which the two are selected. Support for the term -- component -- is found, for example, on page 10, line 22 of the instant application. Accordingly, amended claim 1 is believed to resolve the issue raised by the Examiner.

Contrary to the Examiner's conclusion, claims 2-5 properly depend from claim 1 because they set forth specific combinations of the components of the pharmaceutical composition, i.e. α-lipoic acid and ambroxol in claim 2, α-lipoic acid and ACE inhibitor in claim 3, ambroxol and ACE inhibitor in claim 4 and all three components in claim 5.

Claim 1 has been amended to call for at least one ACE inhibitor and this is believed to resolve the issue of antecedent basis for claims 3-5 and 7 in claim 1.

Reconsideration of the matter as between claims 8 and 9 and relating also to claims 31-36 and 25-30 is respectfully requested. While routes of administration are called for in claim 8, claim 9 calls for particular structures in which the pharmaceutical composition can be provided. Applicants are believed to

be entitled to these two types of claim definition as applied to their pharmaceutical composition to provide the proper scope of protection for their invention.

Claims 8 and 25-30 are amended to delete "buccal" in response to the Examiner's objection. Applicants do not agree that having nasal, relating to the nose, and pulmonal, relating to the lungs, in the claims renders them confusing.

Claims 10-12 and 37-44 have been amended to call for administering the pharmaceutical compositions to a patient, support for this amendment being found, for example, on page 16 at lines 4 and 5 of the instant application.

Turning now to the rejection of claims 1-6, 16 and 17 under 35 USC 103 the three prior art references cited by the Examiner all are non-patent documents in the form of journal publications. Copies of these three references were not included with the Office action. The undersigned attorney telephoned the Examiner to inquire why copies of these references were not furnished by the PTO. The Examiner indicated that copies of the references were not included with the Ofice Action because they were cited in the two co-pending and related applications identified on page 8 of the Office Action. However, this reason for not providing copies is questioned in view of MPEP § 705.05(a) which provides "copies of references cited in continuation applications if they had been previously cited in the parent application are not furnished". The

instant application is not a continuation of the applications identified on page 8 of the Office Action.

The undersigned attorney reported the foregoing to the European patent attorney for applicants who reside in Germany. In attempting to obtain copies of the prior art references from applicants, the European attorney initially was informed by them that the co-pending patent applications had been transferred to another owner who at that time was not willing to provide the requested copies of the prior art references. Subsequently the European attorney has been able to obtain the name of a German patent law firm representing the new owner of the co-pending applications and has requested from them copies of the prior art references. Assuming the references can be obtained in this manner, applicants will respond to the rejection of claims 1-6, 16 and 17 under 35 USC 103 shortly by way of a supplemental response to the Office Action.

In view of the change in ownership of the applications forming the basis for the double patenting rejection on pages 8 and 9 of the Office Action, this matter need not be addressed.

The Abstract has been shortened as requested by the Examiner.

Favorable action on this application is respectfully requested.

Respectfully submitted,

By: Martin G. Linihan
Martin G. Linihan
Reg. No. 24,926

Hodgson Russ LLP
One M&T Plaza, Suite 2000
Buffalo, New York 14203
Telephone: 716-848-1367
Dated: October 13, 2005

Exhibit A

Were you looking for ***pro drugs***

Web Results

Page 1 of 16,023 results containing **prodrugs** (0.10 seconds)

PEA - Pharmaceutical Conferences - a division of FRA, LLC

Pharmaceutical Education Associates provides an unbiased forum for the exchange of ideas and ... All in within ©2002-2005 FRA, LLC Site designed and developed by Web Station, Inc.

www.pharmedassociates.com/drug.asp Cached page

Brochure: The Basics of Prodrugs

... Department of Medicinal Chemistry University of Florida To Order, click here! About the Course: **Prodr** pharmacologically inactive derivatives of an active drug designed to ameliorate some ...

aaps.org/meetings/distance/cdroms/prodrugdelbroch/index.asp?size=small Cached page

Order Form for "Basics of Prodrugs" CD-ROM

CD-ROM ORDER FORM The Basics of **Prodrugs** Please print, complete, and FAX or mail this form shown below. Name: If you are an AAPS member, please enter member number: Organization: Add

aaps.org/meetings/distance/cdroms/prodrugdelbroch/prodrugreg.html Cached page

Show more results from "aaps.org".

Glossary of Medicinal Chemistry

The full text of the IUPAC glossary of terms used in medicinal chemistry International Union of Pure ... Int Union of Pure and Applied Chemistry Chemistry and Human Health Division Medicinal ...

www.chem.qmul.ac.uk/iupac/medchem Cached page

Novel and Targeted Prodrugs

... effect profile as compared to conventional therapies conventional therapies ‰ ‰ Twinstrand **Prodrug** genetic damage or bone Twinstrand **Prodrugs** will not cause genetic damage or ...

www.twinstrand.com/files/TTIMay2005.pdf Cached page PDF file 10/11/2005

Effect of Hydroxypropyl Beta Cyclodextrin Complexation on Aqueous ...

... stability, and in vitro corneal permeation of acyl ester **prodrugs** of ganciclovir (GCV). Aqueous solubilit of acyl ester **prodrugs** of Ganciclovir (GCV) were evaluated in pH 7.4 isotonic ...

www.aapspharmscitech.org/view.asp?art=pt040345&pdf=yes Cached page

Targeted Brain Delivery of 17ß-Estradiol Via Nasally Administered ...

... delivery of the **prodrugs** compared to an equivalent intravenous dose. It was determined that wat **prodrugs** of 17ß-estradiol can be administered nasally. These **prodrugs** are capable of ...

www.aapspharmscitech.org/view.asp?art=pt030105&pdf=yes Cached page

Show more results from "www.aapspharmscitech.org".

New Water Soluble CC-1065 Analog Prodrugs: Design, Synthesis and ...

New Water Soluble CC-1065 Analog **Prodrugs**: Design, Synthesis and Evaluation R. Y. Zhao*, R. Chari, M. Miller, K. Whiteman, B. Leece, V. Goldmakher, C. Dionne and R. Lutz ...

www.immunogen.com/zhaoACS0802.pdf Cached page PDF file

Enzyme-Catalyzed Activation of Anticancer Prodrugs -- Rooseboom et al ...

... as reviewed by Patterson et al. (1999). c. Activation of **Prodrugs** by Cytochrome P450. Although mos **prodrugs** were not designed as **prodrugs**, these chemotherapeutic agents have been shown to be ...
pharmrev.aspetjournals.org/cgi/content/full/56/1/53

..:: CompuDrug Inc. ::..

... **ProDrugs** RetroMEX HPLC Analythics EluEx pKalc PrologD PrologP Pallas HazardExpert MetabolExp pKalc PrologD PrologP TPSA Rule of 5 RetroMEX ToxAlert Plug-in ISIS Plug-in Codessa Pro Demo Dow Newsboard ...
www.compudrug.com Cached page

Didn't get the results you expected? Help us improve.

---

prodrugs Search

on the filing date of any parent U.S. application which priority is claimed. Examiners should f interest all material prior art having an effecling date after the filing date of the U.S. parent ation but before the actual filing date of the ation being examined.

owed applications should generally contain a n of pertinent prior art for printing in the patent, f no claim presented during the prosecution was ered unpatentable over such prior art. Only in nstances where a proper search has not revealed ior art relevant to the claimed invention is it riate to send an application to issue with no art In the case where no prior art is cited, the examust write "None" on a form PTO-892 and insert e file wrapper. >For Image File Wrapper (IFW) ing, see IFW Manual section 3.7.< Where ref- have been cited during the prosecution of parlications and a continuing application, having ly cited references, is ready for allowance, the ferences of the parent applications should be n a form PTO-892. The form should then be in the file of the continuing application. >For File Wrapper (IFW) processing, see IFW Manion 3.7.< See MPEP § 1302.12. In a continued tion application filed under 37 CFR 1.53(d) not necessary to prepare a new form PTO-892 c form from the parent application is in the e wrapper and will be used by the printer.

continuation and continuation-in-part applicae parent applications should be reviewed for l prior art.

ants and/or applicants' attorney in PCT national applications may wish to cite the citations from the PCT International Search y an information disclosure statement under .97 and 1.98 in order to ensure consideration aminer.

e instances where no information disclosure has been filed by the applicant and where s are cited in the International Search Report r a copy of the documents nor an English n (or English family member) is provided, ner may exercise discretion in deciding o take necessary steps to obtain the copy nslation.

of documents cited will be provided as set MPEP § 707.05(a). That is, copies of documents cited by the examiner will be provided to applicant *except* where the documents:

(A) are cited by applicant in accordance with MPEP § 609, § 707.05(b), and § 708.02;

(B) have been referred to in applicant's disclosure statement;

(C) are cited and have been provided in a parent application;

(D) are cited by a third party in a submission under 37 CFR 1.99 >(MPEP § 1134.01)<; or

(E) are U.S. Patents >or U.S. application publications< which are cited at allowance (MPEP § 1302.04).

See MPEP § 707.05(e) regarding data used in citing references.

707.05(a) Copies of Cited References [R-2]

Copies of cited references (except as noted below) are automatically furnished without charge to applicant together with the Office action in which they are cited. Copies of the cited references are also placed in the application file for use by the examiner during the prosecution.

Copies of references cited by applicant in accordance with MPEP § 609, § 707.05(b) and § 708.02 are *not* furnished to applicant with the Office action. Additionally, copies of references cited in continuation applications if they had been previously cited in the parent application are not furnished. The examiner should check the left hand column of form PTO-892 if a copy of the reference is not to be furnished to the applicant.

Copies of foreign patent documents and nonpatent literature (NPL) which are cited by the examiner at the time of allowance will be furnished to applicant with the Office action, and copies of the same will also be retained in the file. >For Image File Wrapper (IFW) processing, see IFW Manual section 3.7.< This will apply to all allowance actions, including first action allowances and *Ex Parte Quayle* actions.

In the rare instance where no art is cited in a *>continuing< application, all the references cited during the prosecution of the parent application will be listed at allowance for printing in the patent.

To assist in providing copies of references, the examiner should: